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United States  
Department of  
Agriculture

Office of  
Governmental  
and Public Affairs

# Speeches and Major Press Releases

September 22 - September 26, 1980

# Speeches

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U.S. Department of Agriculture • Office of Governmental and Public Affairs

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**Excerpted remarks prepared for delivery by Secretary of Agriculture Bob Bergland before the Chicago Council on Foreign Relations, Chicago, Illinois, Sept. 24, 1980.**

We are recording the largest gain in the export of American farm products since that trade began at Jamestown in the early 1600's.

The sale of \$40 billion in farm products to foreign markets this fiscal year represents an increase of \$8 billion over last year. This is a 25 percent gain in one year and a 75 percent gain in four years. It demonstrates for all to see that American farmers are not dependent on the Soviet Union for a continued expansion in our export market for agricultural products.

Last November, before the partial suspension of exports to the Soviet Union, the Department of Agriculture forecast officially that U.S. farm product exports this fiscal year would approximate \$38 billion. By substantially exceeding what we considered to be a rosy outlook, American farmers have effectively declared their independence from the up-and-down Soviet market. Their export achievement in the past 12 months has far overshadowed all of our earlier expectations of sales to the USSR. And these are solid gains that we can maintain and build upon--not dependent on a crop failure in one country.

The expansion in our agricultural exports is broadly based. Both value and volume are at record highs. Every commodity group shared in the increase--grains, oilseeds, cotton, fruit and vegetables, tobacco, livestock, dairy, and poultry. And our markets in all parts of the world have contributed to this gain--except, of course, the Soviet Union.

One market is worthy of special note since it represents the opening of a great and populous nation to western commerce after decades of economic isolation. In 1976, the China market was virtually at zero as far as U.S. agriculture was concerned. In 1977, President Carter reaffirmed the Shanghai Communique as a basis for improved relationships between the two countries, and the following year we began exchanges in the field of agriculture.

In 1979, the Chinese bought almost \$1 billion in U.S. farm products. In the year just ending, their purchases will approach \$2 billion.

It is significant that during this same period our sales to Taiwan have also continued to grow. Since 1976, these exports have more than doubled. The fact is that the last four years have brought sharp increases in U.S. agricultural exports to both China and Taiwan. From a combined total of only \$474 million in 1976, the two markets now account for close to \$3 billion in U.S. farm product sales.

American farmers send into export about one-fourth of their total product by value. I don't know of another major sector of American commerce that contributes so high a share to the strengthening of our position in the world economy. By the same token, U.S. farmers depend on the export market for a major part of their income.

Agricultural trade generates millions of jobs--on the farm and throughout the economy.

The expansion of export markets for the products of our agriculture continues to be a major goal of this administration. It was a major goal in 1978 when the Agricultural Trade Act became law. It remains a major goal today. We have seen what we can do by working together--farmers, their organizations, Congress, and the administration.

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# Speeches

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U.S. Department of Agriculture • Office of Governmental and Public Affairs

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**Excerpted remarks prepared for delivery by Anson R. Bertrand,  
Director of Science and Education, before the National Soil  
Conservation Service conference, Rapid City, South Dakota,  
September 25, 1980**

I submit to you that the successful and productive interaction of soil and water conservation research and soil and water conservation technology is our last best hope to meet the tremendous pressures that are being placed upon our land resource base. These pressures include the expansion of our agricultural export trade, the conversion of prime agricultural land to urban use, and the competition for water--to name a few.

People, institutions, resources, and natural ecosystems will be affected far into the future by the things that are done or not done as the result of the interaction between land conservation research and technology.

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The rate of technological progress in agriculture, which has meant tremendous increases in productivity during the last half century, is slowing down. We don't see anywhere near the great yield increases today that we saw in the 40's, 50's and 60's. And we see this levelling off not only in the United States but all around the world.

As an agricultural scientist, I am deeply concerned about this technological slowdown, that it is unnecessary and represents a failure of adequate support for agricultural research.

If we continue to take good land out of farming, if our yields level off, if soil erosion continues unabated, if demand continues to increase, and if we are unable to turn this around through research, some day we will run short of food and fiber. It may come first in a drought year, or when an unexpected crop disease takes its toll--something like Southern cornleaf blight of a few years ago or the stem rust that nearly wiped out durum wheat even earlier. Secretary of Agriculture Bob Bergland has called current trends "a collision course with disaster."

But trends need only serve as warning signals, not necessarily indicating an inevitable outcome. A wise nation, heeding the warnings, can take steps to turn the trends around.

### **How long do we have?**

Economists warn that two successive years of bad harvests in any of the major grain producing nations could cause "widespread famine and political disorder" in poor countries, and "would severely disrupt a fragile world economy already weakened by energy shortages and rampant inflation." Other organizations, such as the United Nations Council on Environmental Quality, and the World Bank, have issued similar warnings.

Droughts and long periods of extreme heat this year in some areas have brought a recall of the Dust Bowl days and questions in the minds of many. This year some farmers have harvested their grain to feed their animals because of parched rangeland, and promising grain crops have shriveled.

A recent report by the Presidential Commission on World Hunger and The Global 2000 report state that unless the United States and other countries act now to increase long-range agricultural productivity, a global food crisis, worse than the present energy situation, is likely within the next 20 years.

### **How do we head-off a global food crisis?**

There are a few basic steps we can take right now that might start us down the right road.

One is that we accept our basic natural resources as finite and stop wasting them, abusing them, and diminishing them. My own arithmetic and common sense tell me that we had better take care of the good agricultural land that we have left.

I am convinced that the quality of life future Americans enjoy will depend primarily on how well we manage and use our agricultural and forest resources now . . . and in the years immediately ahead. We have an opportunity to engineer our future through the choices we make.

A second principle we might agree on is that we need to get on with the job of research. We do not have all the answers . . . we still have a lot to learn. The stock on our technology shelves is looking pretty

threadbare.

Today we lack the knowledge of underlying principles to guide applied research toward new technological advances. The plain fact is that we do not know enough today to significantly increase the efficiency and effectiveness of our food production process much beyond current limits.

We still have a lot to learn about forest management and utilization of forest products.

We still have not yet completed our audit of conservation tillage techniques, including no-till.

Soil erosion and water constraints have reemerged as major problems and may very well be even more serious than land availability in the future. I have already outlined several examples of the priorities that SEA and SCS have given to research in these areas. I hope that we can increase our interaction to meet the research need.

Research and education are the only effective weapons with which we can meet the challenges ahead. Research and education are investments in the future. They are the way to expand our resources, both physical and human.

Our society is depending on the output of research and education. Knowledge produced by the research establishment this year will be important to our whole society over the next quarter century. Industry will depend on it for production and sales in an increasingly competitive world economy. Workers will depend on it for real increases in their standards of living.

Each partner needs the other. Interaction is essential.

In his recent book, "The Wooing of Earth", Rene Dubos suggest a way of managing the future. He said, to "think globally and act locally." Thinking globally and acting locally is both the record and the challenge of our agencies. Like Dr. Dubos, I am an optimist, and I share his faith that we can and will meet the challenges ahead--working together.

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# Speeches

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U.S. Department of Agriculture • Office of Governmental and Public Affairs

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**Excerpted remarks prepared for delivery by Anson R. Bertrand, Director for Science and Education, before the International Symposium of Nutrient Cycling in Agricultural Ecosystems, University of Georgia, Athens, Georgia, September 22, 1980.**

Throughout early history, man's ability to support himself on this planet was tied to the natural plant nutrient cycle, and the consequent availability of food. In more modern times we have altered that cycle. We have identified 16 elements needed for plants and other organisms to convert sunlight to other forms of usable energy. These 16 elements make up the nutrient cycle. Special attention is given to nitrogen, phosphorus and potassium which are the most commonly deficient elements.

In recent decades the public has generally lost sight of the cycle's importance. There is a hazy perception that intensive modern agriculture, with its fertilizers, pesticides and mechanized irrigation, has risen above constraints imposed by the natural nutrient cycle

Unfortunately, that is not the case.

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There is a growing shortage of good quality organic matter for use in maintaining and improving the productivity of our agricultural soils.

And with increasing demand for these materials, agriculture is going to have to justify its need for every ton of organic material it gets.

The answer is careful scientific work that can insure maximum long-term productivity from the resource base.

We cannot go back to the subsistence agriculture of the past, simply because that would mean taking the path back toward famine for large numbers of people in the world. The demands on agriculture will increase not decrease. So we must find ecologically sound ways to further increase the productivity of our farms.

As always, research is the key to the future.

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I am convinced that an increasingly important part of the research needed to resolve the nutrient problem will come from multi-disciplinary teams of scientists. I know that we are funding more and more of these teams through the Science and Education Administration (SEA), and I expect the trend will continue.

For a century or more, modern scientists have been specialists. Each of us has focused on one aspect of science--such as plant physiology, soil chemistry or soil physics--and most of us have delved as deeply as we could into the mysteries of some particular area within that specialty.

Thomas Jefferson may have been the last man to have known everything there was to know in his time about American agriculture. This was due only partly to the fact that Jefferson was a brilliant man, an encyclopedic reader and careful scientist in his own right. Jefferson also lived in a time when there was far less to know.

The explosion of knowledge in the last 200 years has literally forced Jefferson's successors into scientific specialization. But something important was being lost in the process--awareness of the interrelationships between things. None of the natural phenomena we study exists in a vacuum by themselves. They are constantly interacting.

Now we are finding that we cannot afford to stay so compartmentalized. As we stretch to the limits of our specialties, we find that our research compartments are interrelated too. Now we come full circle back to Jefferson's broad understanding--but we have to do it by gathering teams of specialists to embrace the necessary scope, instead of depending on just one brilliant individual.

For the individual, specialization may be carried even further in the years ahead. We may see even narrower specialists than in the past. But the interrelationships will become more important, along with the ability to communicate and interact with other scientists. The multi-disciplinary team seems the logical way to reconcile two seemingly-conflicting needs: the need for delving even deeper into the specifics of basic research and the need to focus more adequately on the interrelationships between specialties.

SEA has entrusted some of its most important work to such multi-disciplinary teams: In animal agriculture, we have teams working on

ways to maximize the use of forage, minimizing the need for resource-intensive grains and oilseeds. In biomass energy, we have many different disciplines examining ways to economically wring fuel from solar-based renewable sources. We have teams working on recombinant DNA technology, using nature's own inherited communications code to prevent disease, increase yields and potentially help solve many other problems.

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We must remember that the intensive agricultural techniques we are currently using are still relatively new in the context of world history. They have yet to stand the test of time.

Other intensive agricultures have emerged, developed long-run problems and faded with their cultures and their peoples from the center stage of world history. The Sumerians, for example, developed the world's first high culture in the Tigris and Euphrates valleys many centuries B.C. Their intensive system of water management and irrigation supplied abundant crops. They built fabulous cities and a wide-ranging commerce. But the system carried with it an ecological flaw. The irrigation deposited salts in the soil, without adequately flushing them out. Over time, this ruined their cropland, reduced their cities and scattered their citizens.

That could still happen to us.

On the other hand, some of the rice-growing regions of China and the Philippines have farming systems that have been maintained essentially unchanged for 3000 years. They can apparently go on indefinitely, with their nutrient cycles in full balance. The problem is that these are labor intensive systems that provide little surplus and little opportunity to support production of other goods off the farm.

Some major changes in our nutrient cycling appear inevitable over time. Natural processes cannot support the current intensity of modern agriculture; these must be supplemented by inorganic fertilizers mined from finite supplies of gas and oil, phosphate rock and other mined deposits. They, too, have their inevitable impact on the ecosystem--especially on water quality. We know that we are producing too little organic matter or removing too much from some of our acres, with resulting problems of erosion and degradation of soil structure.

This is not a prediction of the apocalypse, but rather a frank scientific assessment of the need for more knowledge in the years ahead.

If we want to have an intensive agriculture that can support the world's large and growing population, and support the off-farm production that raises our standard of living above the subsistence level, then we must make sure that our nutrient cycle and all of the other aspects of our farming system can achieve a long-term balance.

The nutrient cycling research being done here in Georgia and at other locations throughout the world will play an important part in achieving such long-term viability.

Knowledge and research have brought us to our current state. If that state is not ecologically stable for the long term, then research must detect the flaws and tell us how to overcome them.

As always, research is the key to the future.

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# Fact Sheet

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U.S. Department of Agriculture • Office of Governmental and Public Affairs

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## **RURAL DEVELOPMENT POLICY ACT OF 1980**

The following fact sheet was issued Wednesday, Sept. 24, upon the occasion of the signing by President Carter of the Rural Development Policy Act of 1980:

### **Rural Development Policy**

- The Secretary of Agriculture will have a leadership role in coordinating nationwide development.
- USDA will develop a national rural development policy and strategy for implementation to be updated annually.

### **Under Secretary of Agriculture for Small Community and Rural Development**

- The office of the Under Secretary for Small Community and Rural Development, a key recommendation in this Administration's Small Community and Rural Development Policy, is created.

### **Planning Assistance**

- The authorization for the Section 111 rural planning grant program is raised from the current level of \$10 million up to \$15 million annually.

### **Circuit Rider**

- The Section 111 rural planning grant authorization is broadened to permit the use of funds for technical assistance purposes. This would facilitate implementation of a circuit rider program to aid rural areas to apply for needed Federal funds.

### **Rural Information System**

- An information and technical assistance system is authorized, with up to \$1 million annually, to disseminate information on Federally sponsored or funded programs to rural communities.

### **Title V Rural Development and Small Farm Research and Extension**

- The Title V Rural Development and Small Farm Research and Extension program are reauthorized through September 30, 1981.

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# Testimony

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U.S. Department of Agriculture • Office of Governmental and Public Affairs

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**STATEMENT  
of  
Carol Tucker Foreman  
Assistant Secretary for Food and Consumer Services  
U.S. Department of Agriculture  
Before the Committee on Agriculture  
United States House of Representatives  
September 16, 1980**

Mr. Chairman, I welcome this opportunity to discuss the FDA and USDA actions on the problem of nitrite and to examine some of the issues of food safety policy that have been raised by this experience. For three and a half years now I have been Assistant Secretary of Agriculture with responsibilities for enforcing the health and safety provisions of the Federal Meat and Poultry Inspection Acts. During this period, the evidence on the potentially adverse health effects of nitrite has posed some of the most difficult and controversial questions that food regulatory agencies have ever had to face. I sympathize with Commissioner Goyan who had the misfortune of entering the drama in midstream.

I can assure you that FDA and USDA have not sought the limelight on this particular issue. From the outset it has been a regulator's nightmare--with bacon and breakfast, hotdogs and baseball on one side, and the potential risk of cancer on the other. The last thing we wanted was to turn nitrite into a cause celebre. We have attempted to steer a calm, open, and rational course. Much of the heat has come from other quarters, including some Members of Congress. In today's hearing, I hope that we will have the reasoned and constructive discussion that the question of nitrite deserves.

Two years ago, I testified with Donald Kennedy, who was then FDA Commissioner, before Agriculture Committees in both the House and the Senate on the subject of nitrite. A month earlier, our Departments had announced the results of an animal feeding study conducted under

FDA contract at Massachusetts Institute of Technology by Dr. Paul Newberne. Our announcement, contained in a press release issued on a late Friday afternoon in August, stated that the study "strongly suggests that nitrite produces cancer of the lymphatic system in test animals...and leads us to the concern that nitrite may increase the incidence of human cancer." Almost immediately, doubts were voiced about the validity of Newberne's findings. Some of our own scientists felt there were questions still to be answered. The Congress urged FDA and USDA not to take precipitous action.

We assured the Congress that the study on nitrite was still subject to scientific review and there would be no immediate action to ban the use of nitrite. In my testimony two years ago, I said: "There appears to be some fear that nitrite usage will cease overnight. That fear is unfounded. Final regulatory action by either agency is not imminent." At the same time, the evidence strongly suggested a potential risk to human health. Our agencies had a clear responsibility under the laws which Congress has passed to formulate at least a tentative plan of action in the event the scientific data were valid. Under the plan we ultimately developed, no proposal was made. Instead, we asked Congress to take action to permit continued use of nitrite until alternatives were found.

Now it turns out that neither we nor you will have to take the action we once contemplated. A thorough scientific review of the Newberne study has shown that it does not prove the suspected link between nitrite and cancer. Dr. Newberne had reported that rats fed nitrite developed a significantly higher incidence of cancer of the lymph system than rats on a nitrite-free diet. But a group of independent pathologists have now reviewed the tissue slides from the Newberne study, and they disagree with Dr. Newberne's interpretation. According to their review of the slides, the incidence of lymph cancer in the rats that were fed nitrite is much lower than Dr. Newberne reported. As a result, the study that caused so much concern 2 years ago provides no basis for concluding that nitrite may be harmful to humans, and no basis for regulatory action at this time to phase out the use of nitrite.

I can understand the concern of the committee over what has happened. At first glance, it might appear that the government has changed course over the past 2 years. In August 1978, we announced to

the public that it might be necessary to discontinue to use nitrite as a curing agent in meat and poultry. Two years later we said, "Never mind."

The only problem with this interpretation of events is that from the very outset we stressed the tentative nature of the Newberne findings. We were given a startling report by Dr. Newberne. We were faced with the task of settling upon a course of action that met the needs of the public and the existing law in the event that Newberne findings were confirmed.

And even now, we cannot tell the public that nitrite has a completely clean bill of health. Although a direct link between nitrite and cancer was not borne out by the review of the Newberne study, no one is able to say nitrite is safe. We are still left with the separate problem of nitrosamines. We know that nitrite can combine with other substances to form nitrosamines, which have clearly been established by animal studies to be powerful carcinogens. We have taken regulatory action to deal successfully with the problem of preformed nitrosamines in bacon, but the possibility still exists that nitrosamines can be formed through the combination of nitrite with amines and amides in the human digestive tract. For this reason alone, the use of nitrite as an added substance in our food supply will continue to be a matter of significant concern to the agencies under existing law.

I am sure the committee is aware of the great complexity of the nitrite issue. It has involved some difficult questions of law, public health, scientific evaluation, and public disclosure. Given the information that we had back in the summer of 1978, I remain convinced that the tentative plan we announced then represented the best avenue for resolving these difficult questions. I am also convinced that at every step of the way we acted rationally and even creatively to strike a prudent public policy in a unique situation. To understand our choices when we learned of the Newberne findings, it is necessary to first understand our obligations under the present food safety laws. After reviewing the legal framework in which we must operate, I will turn to the Newberne study itself, and our attempts to deal with it. I will conclude with a discussion of some of the significant issues that emerge from our experience with nitrite.

## **I. THE LEGAL FRAMEWORK**

Beginning with the passage of the first pure food laws in 1906, Federal statutes have contained strict provisions with regard to substances that are added to food. We tend to associate passage of the original meat inspection act with Upton Sinclair's "The Jungle." The story has been told of how Congress responded to public alarm over the unsanitary conditions in the nation's meat packing houses. But the legislative history shows that Congress was just as concerned over the health risks that might result from the deliberate addition of preservatives and colorings. Final hearings on the proposed legislation were devoted almost entirely to testimony from the food industry and scientific and medical authorities on the effect of such added substances as boric acid, salicylic acid, sulphur dioxide, formaldehyde, and saltpeter (which, incidently, is potassium nitrate used for the same purpose as sodium nitrite). The act passed in 1906 contained the following provision: "Inspectors shall label, mark, stamp, or tag as unwholesome, or which contain dyes, preservatives, or ingredients which render such meat or meat food products unsound, unhealthful, unwholesome, or unfit for human food, and all such condemned meat food products shall be destroyed for food purposes."

The present laws are just as strict with respect to added substances. However, over the years, they have become more complex as the Congress has passed amendments to create different categories depending upon its use. Nitrite can be considered a "food additive," a "color additive," or a "prior sanctioned substance" depending upon the product in which it is used and the function it serves.

### **Food Additives and Color Additives**

In everyday speech, anything added to a food may be called a food additive. Under the law, however, the term "food additive" has a narrow and more precise meaning. The Food, Drug and Cosmetic Act defines food additives as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food..." The Act then goes on to state that the term does not include pesticides, new animal drugs, color additives, or prior sanctioned substances.

The Food, Drug and Cosmetic Act defines the term "color additive" to mean "a material which is a dye, pigment, or other substance...and when added to a food...is capable...of imparting color thereto." The act then goes on to state that a color additive does not include any material which the Secretary, by regulation, determines is used solely for a purpose or purposes other than coloring.

### **Prior Sanctioned Substances**

A "prior sanctioned substance" is one that is used in accordance with a sanction or approval granted prior to September 6, 1958. The existence of a prior sanction depends upon the specific use of the substance. If a specific use was approved before September 6, 1958, then prior sanction would apply. An example would be the use of nitrite as a preservative in certain red meat products. But if that same substances were put to a new use, which was not approved before September 6, 1958, then prior sanction would not apply.

In its most common use today--as a curing agent in bacon, hotdogs, ham, corned beef, pastrami, and other red meat products--nitrite is considered a prior sanctioned substance. The agencies have determined that this use in red meat was approved by USDA many years ago. As early as 1925, USDA had regulations limiting the residual quantity of sodium nitrite in meat in quantities up to 200 parts per million. However, there are other current uses of nitrite in which the substance is regulated not as a prior sanctioned substance but as a food additive. These include its use in fish, pet food, home curing mixes, and certain imported cheese. The question of whether nitrite is a food additive or a prior sanctioned substance in poultry products is now being reviewed by USDA.

Any possible color additive status for nitrite is now being considered by FDA as the result of a court action. A suit was brought against USDA and FDA contending that when used in bacon, nitrite is a color additive or a food additive, and not a prior sanctioned substance. Color additives are food additives are subject to a separate FDA approval system which places the burden on manufacturers to establish the safety of a substance before it can be used. According to an argument made in the lawsuit, the present use of nitrite is illegal because it has not been through the FDA approval process for additives. USDA and

FDA argued, however, that nitrite sanctioned by USDA for use as a preservative in red meat products, including bacon, prior to September 6, 1958, and was not a color additive. Both the U.S. District Court and the Court of Appeals upheld the government's position regarding food additives. The question of whether nitrite might be regarded as a color additive as well was remanded to FDA for administrative consideration.

### **The Delaney Clause**

When nitrite is regulated as a food additive or a color additive, it is subject to the Delaney Clause, a well-known and much discussed provision of the Food Additive Amendments of 1958 and the Color Additives Amendment of 1962. The Delaney Clause prohibits the use of any food additive or color additive shown "to induce cancer when ingested by man or animals or shown to induce cancer when man or animals are exposed to it by any 'appropriate test.'" One of the frequent criticisms of the Delaney Clause has been its lack of flexibility. Once it has been concluded on the basis of adequate scientific analysis that an additive has been shown to induce cancer in animals, that substance must be banned. There is little room for administrative discretion.

The Delaney Clause does not permit any consideration of the benefits of substances classified as food additives or color additives. It sets a strict, risk-based standard. In this respect it differs from the provisions in the law that govern other categories of food substances, such as pesticides, unavoidable contaminants, and naturally occurring substances. In regulating a pesticide such as dieldrin or an unavoidable contaminant such as PCB, the FDA is permitted to weigh the benefits of different regulatory approaches and then decide what level of these substances to allow in food before it is considered adulterated. An unavoidable contaminant is one that has become so ubiquitous in the environment that there are no feasible short-term means of keeping it out of the food supply. An example would be the contamination of the streams, lakes, and oceans that results in low levels of potentially toxic substances in fish. But when a substance is deliberately added to food, the Congress has created a different standard. When a substance is a food additive or color additive, the Delaney clause applies, and there is no flexibility. There is no provision in this law for the weighing of benefits. Further, no amount of a substance, however small, can be

permitted once it has been found to cause cancer in animals. Congress established this zero-tolerance because of the scientific assumption that there is no safe level of exposure to a cancer-causing substances.

### **The Federal Meat Inspection Act**

In its most common use--as a curing agent in red meats--nitrite is not subject to the Delaney Clause. I believe that this has been the most misunderstood aspect of the whole controversy over nitrite. Because of the use of nitrite in red meat was approved before September 6, 1958, it is excluded from the Delaney Clause as a prior sanctioned substance. However, nitrite used in red meat is subject to the adulteration provisions of the Federal Meat Inspection Act, which in several important respects Congress constructed to be just as strict as the standard set by the Delaney Clause.

Under the Federal Meat Inspection Act, a product is considered adulterated "if it bears or contains any poisonous or deleterious substances which may render it injurious to health." In this Act, too, Congress has distinguished between added substances and substances that occur naturally in the product. In the case of naturally occurring substances, Congress has declared that a product is not adulterated "if the quantity of such substance...does not ordinarily render it injurious to health" (emphasis added). However, Congress has set a more stringent standard for added substances. If the substance is added, a product is adulterated "if it bears or contains any poisonous or deleterious substance which may render it injurious to health" (emphasis added). The courts have consistently interpreted the "may render injurious" standard to mean that a product is adulterated if there is a reasonable possibility that it may be injurious to health (the leading case interpreting this standard is *United States v. Lexington Mill and Elevator Co.*, 232 U.S. 399 (1914)). The standard Congress has set in the Meat Inspection Act is therefore more difficult to meet than the Delaney Clause, which requires a specific finding that a substance causes cancer in humans or animals before regulatory action is triggered. In the Meat Inspection Act, Congress has said that a substance fails to meet the test of acceptability if it may be injurious to health for any reason.

However, the adulteration standard Congress has set for added substances under the Federal Meat Inspection Act is similar to the Delaney Clause in two key respects. First, Congress has written a standard based entirely on risk. You have not provided any authority for the Executive Branch to consider the economic or health benefits of a substance in administering the law. Added substances that may cause harm to humans are prohibited in meat regardless of any benefit they may confer. Second, if an added substance poses any risk, the law does not permit it in any amount. Congress has permitted "quantity" to be taken into account in regulating naturally occurring substances, but the law makes no mention of quantity with respect to added substances. These provisions have been in the law since its inception. Congress has amended the Meat Inspection Act several times subsequently and on several occasions has discussed the adulteration provision. However, in each case Congress has chosen not to alter the provision. The intention of Congress that the Executive Branch apply a strict standard in permitting the use of food additives is abundantly clear.

### **Constructing a Rational Policy: The Dilemma Over Botulism**

Nitrite, whether its use falls under the Delaney Clause or under the adulteration provisions of the Federal Meat Inspection Act, is an added substance and unquestionably is subject to a strict standard. If there is evidence that an added substance causes cancer in animals, or that it otherwise may be injurious to human health, then there is no choice under existing law but to prohibit the use of that substance. When we were first informed about the findings of the Newberne study, it appeared that there was a strong possibility such evidence did exist concerning nitrite, and that its use would have to be banned. However, we were confronted with a serious dilemma. While it appeared that nitrite may have harmful human health effects, it also has the valuable effect of preventing botulism, a deadly form of food poisoning. According to the law, nitrite would have to be banned if it were shown to present a risk to human health. But at the same time, the prohibition of nitrite might expose people to other potential risks.

Part of the problem was that the food industry and consumers had grown accustomed to the unique preservative qualities of nitrite. It is clear that there are alternative means of preventing botulism--such as

refrigeration, canning, drying, and pickling. However, we believed that time was needed to implement those alternatives throughout a very large and diverse industry.

### **Struggling with Options**

Faced with this dilemma, we struggled to find a course that would protect the public health, meet our obligations under the law as Congress wrote it, and, if at all possible, provide for a period of relative calm in which the Newberne study could be evaluated and the issues it raised could be discussed. We knew that this would be no easy task.

We first learned of the Newberne findings in May 1978, and it was about the worst news one could imagine. Here was a study showing that a substance might cause cancer in humans. It appeared to be a good study, conducted under FDA contract by a respected researcher at one of the nation's top universities. It concerned a substance that was no ordinary additive, but one that had been used for centuries, a substance that was now used in such popular products as bacon, ham, and hotdogs. The economic implications were immense--more than \$10 billion annually in the red meat industry alone, and more than 10 percent of the nation's food supply. To make matters worse, this substance, which might cause cancer, had the health benefit of preventing another deadly disease.

It is not hard to picture the intense period of activity that ensued at FDA and USDA. We examined every conceivable option ranging from no action to an immediate ban. We rejected the former because it would clearly violate our responsibilities under an act of Congress. We rejected the latter because it could pose the significant public health risk of botulism poisoning and would result in severe economic disruption. But any action short of a move to prohibit nitrite ran up against the strict adulteration provisions of the law. We also labored under the tremendous time pressures. We felt we could not sit for long on a study that had such highly charged implications. As early as May 8, 1978, an item appeared in "Food Chemical News" stating that 12 "MIT studies indicate induction of lymphomas by sodium nitrite in test animals." As a result, other reporters from the general press were expressing interest. We believed and believe that the worst possible outcome would have been for news of the study to leak out in a

distorted fashion. The only thing worse than having the report was to have press and television spread the alarm that the government was suppressing evidence that hotdogs and bacon caused cancer.

The root of our dilemma was legal: the strict adulteration standard of the Federal Meat Inspection Act and the Food, Drug, and Cosmetic Act. So we turned to our lawyers to see if there was some way around the standard. We needed a legal alternative to an outright ban or to tossing the entire matter back into the hands of Congress. The course we finally decided upon was to propose an eventual phaseout of nitrite. In view of its health benefits, nitrite would continue to be used until alternative substance were developed. We believe that this course gave us some breathing space gave public notice of the action that eventually might be necessary, and avoided the untenable position of doing nothing to protect the food supply.

We believed we could rely upon the administrative process to give us some of the time we needed. I discussed this aspect of our plan in the hearings two years ago:

"We believe, in fact, that the administrative process provides an excellent opportunity for a considered, sensible, and useful analysis and debate, both of the Newberne study and of the proposed course of action on nitrite. It will also stimulate intelligent public consideration of the important issues involved in dealing with the safety of our food supply in general."

### **The Attorney General's Opinion**

We recognized, however, that our tentative course of action rested on an untested interpretation of the law. So in August 1978, we wrote to the Attorney General requesting an opinion of our legal position. We proposed two theories. First, USDA argued that since the general intent of the law is protection of the public health, we should be allowed to balance the health benefits of nitrite (prevention of botulism) against their potential harm. Second, USDA argued that even though there was no discretion in the law as to whether to ban a cancer inducing additive, the law does not specify when a ban must take effect; therefore, FDA had the discretion to permit the use of nitrite until alternatives were developed. The Attorney General rejected both arguments, stating that the wording of the statutes, the legislative

history, and existing case law all demanded that, upon finding that nitrite is carcinogenic, the agencies had no alternative but to proceed with orderly removal of this substance from commerce. At this point, Mr. Chairman, I would like to have the memorandum of the Attorney General's opinion placed in the record.

With the Attorney General's opinion in hand Mr. Chairman, we could follow three courses of action. First, we could ignore the demand of Congress as expressed in the law and do nothing. Clearly, that was unacceptable to officials sworn to uphold the law. Second, we could await verification of the Newberne study, propose a ban on nitrites, and then drag the process out indefinitely. That, too, ran afoul of our oaths of office. There was another problem with these first two courses of action. The meat processing industry and pork producers were understandably very distressed by the revelation of Newberne's study and the Attorney General's opinion. Doing nothing left a sword of Damocles hanging over their heads and would surely have an adverse impact on future planning in the industry. Reports from hog producers around the country indicated that there were real fears of a precipitous end to nitrite use and concern that this would cause reduction in hog prices. We, therefore, believed it essential to take a third course: to make our intentions known, to try to reduce uncertainty as much as possible.

We still believed that if the Newberne study were verified, a phase-out was the best public policy course. The administration in March 1979 sent to Congress a legislative proposal to provide for a one-year moratorium on any final regulatory action and for the authority to phase out gradually the use of nitrite if the Newberne study were confirmed. All of these actions, of course, rested on the assumption that the results of the Newberne study would be confirmed. When these results were not confirmed, the legal dilemmas were at least temporarily resolved. But in hindsight, one might well ask: why did we proceed on the assumption that the Newberne study would be confirmed? The answer is that we did not. We proceeded on the assumption that it might be confirmed.

## **II. THE NEWBERNE STUDY**

Let me again emphasize that we attempted to make it clear from the

beginning that the Newberne findings were only tentative. I should also note that the Newberne study had been initiated under a government contract in a previous administration. Government concern over nitrite goes back a number of years in the Department of Agriculture, this concern was given formal structure in 1973 when the Secretary of Agriculture, Earl Butz, appointed an Expert Panel on Nitrite and Nitrosamines. The report was received from Dr. Newberne in May 1978, represented the latest results of government actions on nitrite stretching back a number of years.

In public discussion of the Newberne findings, we were careful to couch our language in such terms as "the conclusions to date," or the Newberne study "strongly suggests." Large, complex scientific studies such as the one conducted by Dr. Newberne must always be put to the test of peer review. This is not a legal requirement, but a matter of accepted scientific practice. When we announced the results of the Newberne study in August 1978, we stated that the study was being made available to the scientific community as well as the general public so that the process of criticism and evaluation could begin. In addition to seeking peer review, we formed an interagency working group for nitrite research. This group was given responsibility of arranging for an independent pathology review of the tissue slides from Dr. Newberne's study.

Even though the Newberne findings could only be considered tentative, there were several reasons why they had to be taken seriously. These reasons include the well-established evidence on nitrosamines, Dr. Newberne's previous study on nitrite, the scope of the Newberne study, the reputation of the researcher and the institution, and FDA's initial review of the findings.

### **The Problem of Nitrosamines**

Scientists have been aware of potential problems with nitrite for many years. In the early sixties, they discovered that fish treated with nitrite and dried at high temperatures contained substances known as nitrosamines. Many nitrosamines, which can be formed at high temperatures when nitrites combine with amines and amides, have been shown to cause cancer in laboratory animals. The discovery of

nitrosamines in fish led the scientific community to investigate the possibility that nitrosamines might also be present in cured meat products. When studies revealed that the risk of nitrosamine formation was especially great in bacon, USDA had to take regulatory action to reduce the amount of nitrite used in curing bacon. This regulatory program for eliminating nitrosamines from bacon has been successful. We have been able to reduce nitrosamines in bacon to below detectable levels and, contrary to fears once expressed by the meat industry, no manufacturers have been forced out of business. However, nitrosamines also occur in a variety of consumer products, and there have been indications they can be formed in the stomach and intestinal tract through the action of nitrite with amines or amides. This body of scientific evidence formed the background to Dr. Newberne's study. His findings simply added a new dimension to already serious questions about nitrite in the food supply.

#### **Dr. Newberne's Earlier Study**

The findings we announced in August 1978 were not the first indication that there might be a direct link between nitrite and cancer. In 1975, FDA had contracted with Dr. Newberne to study the possibility that nitrites might react with amines and amides in food to produce nitrosamines in the digestive tract. In the course of that study, evidence developed suggesting that nitrite, when fed alone (that is, without any amines or amides) to rats, induces a form of cancer called malignant lymphoma (cancer of the spleen, lymph nodes, and cells that make white blood cells). This evidence led FDA to contract with Dr. Newberne for a much larger study to determine whether continuous lifetime exposure of laboratory rats to nitrite causes cancer.

#### **The Scope of the Newberne Study**

The second Newberne study was one of the largest and most comprehensive of its kind ever undertaken. It involved 1,381 rats that were fed nitrite in varying amounts and in a variety of diets. It involved an additional 573 rats used in control groups. The study was designed to show the relationship between dose (the amount of nitrite fed) and response (the occurrence of cancer in the animals fed nitrite). Although it is often mis- understood by the general public, the use of

large doses in an animal study is a scientifically accepted method of determining whether a substance causes cancer. Cancer researchers understand that high doses are not representative of human exposure, and are not intended to be. High doses are used so that enough cancers will be produced to make the effects of a substances identifiable. The results of the experiment then provide a basis for estimating, by statistical means, how many cancers might result from the lower doses to which humans might be exposed.

The results of the study indicated that nitrite produced a statistically significant increase of cancer of the lymphatic system. The combined incidence of lymphatic cancer in the groups that were not fed nitrite was 7.9 percent, and the incidence in groups fed nitrite was 12.5 percent (or 50 percent greater than the control groups). The pattern of the tumors appeared to rule out the possibility that the carcinogenic effect of nitrite occurred by the formation of nitrosamines. Nitrosamines typically produce cancers at multiple sites (in the lungs, digestive tract, liver, and nervous system), and have not been known to produce lymphatic cancer exclusively. In addition to the evidence of lymphatic cancer, the study pointed to other potential toxic effects from nitrite, including enlargement of the heart and alterations in various parts of the immune system.

### **Reputation of the Researcher**

Our concern over the possible adverse health effects of nitrite was reinforced by the reputation of the researcher. Dr. Newberne and his laboratory are well-regarded within the scientific community, and he has had a strong track record as a cancer researcher. The Massachusetts Institute of Technology, where the study was conducted, is one of the nation's preeminent centers of scientific research. Moreover, Dr. Newberne is known to be conservative in his interpretation of data that suggest carcinogenicity. In the Senate hearings on nitrite in September 1978, Newberne was described by another cancer researcher as "a highly respected and very able toxicologist and pathologist who is an objective scientist and is not known as an alarmist or an extremist."

### **FDA's Preliminary Evaluation**

Although scientific confirmation of Dr. Newberne's findings had to

await a rather lengthy process of peer review, his study did not go unscrutinized. Before Dr. Newberne was awarded the contract, he had to submit a set of protocols describing in some detail the scope of his study and how he planned to proceed. During the course of his experiments, he was required to submit regular progress reports. Once the study was completed, it was reviewed by a contracting officer to determine whether the protocols had been fulfilled. As part of FDA's Good Laboratory Practices survey, an FDA official visited Newberne's laboratory to observe whether proper procedures were being followed. When questions arose, Dr. Newberne worked to resolve them to FDA's satisfaction.

The steps I have described were all part of FDA's normal review procedures for scientific studies. In this case, however, FDA undertook additional review measures because of the serious public health as well as economic implications of the nitrite study. Even before submission of the final report, FDA began an in-depth scientific and statistical review. Dr. Newberne consulted with FDA as the study neared completion, and FDA scientists and statisticians examined his analysis in draft. FDA scientists also took the step of consulting with their British and Canadian colleagues to explore and resolve certain questions that had arisen in the course of their review. Finally, the FDA Commissioner personally reviewed the study and held a number of sessions with supervisory FDA scientists.

The GAO report on our handling of the nitrite question has commented that in its review of the Newberne study, FDA circumvented its usual review procedures. While I am not in a position to offer a definitive comment on whether this was appropriate, I certainly believe that in view of the serious implications of the Newberne study, special steps were called for. I also believe that the study was subjected to as thorough a review as possible, pending the more lengthy scientific peer review. It should be emphasized that the crucial area of disagreement (the diagnosis of the tissue slides that later undermined the validity of the study) lay outside the scope of any short-term review the government could have conducted. The diagnosis of pathological lesions in animals can involve subjective judgments, and questions concerning diagnosis can be resolved only through a rather

lengthy and painstaking evaluation such as the UAREP review.

### **Criticisms of the Newberne Study**

Despite the factors that appeared to give weight to the Newberne study, strong doubts over its validity were voiced almost immediately after it was made public. In view of this critical storm, it can be argued that we should have paid greater heed to possible objections before announcing even a tentative regulatory plan. It is therefore important to examine the nature of the initial criticism of the study. The arguments that we heard against the Newberne study fall roughly into three categories: arguments questioning the validity of animal feeding studies, arguments questioning Dr. Newberne's laboratory practices, and arguments based on scientific methodology and interpretation.

The animal feeding argument is an old one that seems to surface every time the government prepares to take action to protect the public health. The argument persists, despite a solid scientific consensus that animal feeding studies are a valid method for estimating the risk of cancer in humans. In the hearings 2 years ago we heard one producer representative call for better evidence based on human epidemiology studies. We heard a meat industry representative state that the Newberne study would be valid only if a consumer ate 500 or 600 pounds of nitrite cured meat a day.

It is true that the ideal way to determine whether a substance causes cancer would be to compare cases of people who developed cancer with those who did not, and determine whether there are patterns of exposure that distinguish the two groups. This is known as epidemiological study. The limitation on such studies, however, is the difficulty in finding non-exposed groups to compare with groups that have been exposed. It would be unethical to conduct controlled experiments exposing humans to potential carcinogens, and it is difficult otherwise to determine just who may have been exposed to what in the course of a lifetime.

In the absence of adequate human data, scientists have turned to cancer testing in animals. Humans and animals in general share many basic biological and biochemical mechanisms, including vulnerability to cancer. With one or two possible exceptions, all substances known to cause cancer in humans also cause cancer in laboratory animals. During

a cancer study, test animals are fed high doses so that enough cancers will be produced to make the effects of the substance identifiable, and to take in to account the differences between the test animals' life span and the human life span. If a substance at an ordinary dose caused only one case of cancer in an animal experiment, that case would be lost among the cancers occurring from other causes. Yet that one case would still be significant when projected to a larger population. So animals are fed high doses so that it will be readily apparent whether or not a substance causes cancer. The results can then be adjusted statistically to estimate the risk to humans at lower exposures.

A second area of criticism concerned Dr. Newberne's laboratory practices. When we testified at the Congressional hearings 2 years ago, a great deal was made of the alleged mistakes and oversights that had occurred in the course of the experiment. An animal caretaker was supposed to have fed the wrong diet to a group of rats. A container of urethane, a known powerful carcinogen, was stored on top of the cabinet in one of the rooms. It appeared that some of the equipment and utensils were improperly washed. Other potential problems were mentioned as well. The important point is that all these criticisms of the study were based on an FDA review of the MIT laboratory, and Dr. Newberne was able to resolve any problems to FDA's satisfaction. He also replied at length during the Congressional hearings, and in the GAO report. A careful review of Dr. Newberne's laboratory practices by FDA scientists as well as independent scientists concluded that there were no faults in the laboratory practices serious enough to jeopardize the results of the study.

The third area of criticism--concerning scientific methodology and interpretation--was the most worrisome. Some people questioned the statistical appropriateness of aggregating the results from different groups that had been fed different diets. Others noted that the results of the study might be overstated because of the tendency of animals from the same litter to respond more alike to a test substance. The high incidence of spontaneous lymphomas in the control groups (rats on a nitrite-free diet) also troubled some scientists, leading to speculation that the tissue slides had been misdiagnosed. They were all valid concerns, but they could be resolved only through the lengthy process of peer review. This was particularly true of the question of the

pathological diagnosis. pathology is by no means an exact, quantifiable science. It involves difficult questions of judgment and interpretation by experienced observers, who have been known to disagree over what they see through a microscope. it was in this area that other pathologists later disagreed with Dr. Newberne.

I think it should be emphasized that back in August 1978, we had no way of knowing that several other pathologists would disagree with Dr. Newberne's interpretation of the tissue slides. We knew that the slides would have to be reviewed, but considering Dr. Newberne's outstanding reputation the possibility of significant disagreement seemed remote. It should further be emphasized that almost all the initial criticism concerned other matters, which for the reasons I have mentioned were not considered compelling. One must conclude that there is no easy answer to the question, "What went wrong?" Given the laws under which we must operate and the apparent strength of the Newberne study, the agencies took what they believed to be the only rational--and legal--course of action. It was unacceptable to suppress the existence of the report and it was unacceptable to acknowledge its existence and do nothing. With human health at stake, it was imperative to act conservatively. However, there are still some lessons to be learned from our experience with the nitrite study. The whole episode illuminates some significant public policy issues.

### III. POLICY ISSUES

In announcing today's hearing, Mr. Chairman, you stated that the Committee would go beyond the immediate question of how the nitrite matter was handled, and would discuss the broader issues surrounding our present laws on food additives. I fully agree that the experience with nitrite raises some significant policy questions, and that this is a good occasion to examine them. In my view, there are two broad policy issues that emerge from our recent experience. First, have the legal categories governing added substances grown too complex? Second, is the present risk-based standard for added substances too inflexible?

In examining the present laws on food additives, one is immediately struck by their complexity. Nitrite offers a good case in point. Depending upon its use, nitrite can fall under either the Food, Drug and Cosmetic Act, or the Meat and Poultry Inspection Acts. It can be

regarded as a food additive, a color additive, or a prior-sanctioned substance. It can be subject to the Delaney Clause or not subject to the Delaney Clause. Over the years the food additive provisions of the law have grown so complex that sometimes I am not sure that even the lawyers understand them.

There can be little disagreement that the present scheme should be simplified and clarified. At the same time, we must recognize that the present law may reflect a number of sound policy decisions that are worth preserving. For example, it makes sense that the safety standard for added food substances is higher than the standard for traditional food commodities, such as potatoes. When the Congress set these standards it considered the need for an abundant food supply, and took into account the fact that naturally occurring substances, unlike additives, may not be subject to deliberate control. We therefore would be wise to resist the understandable impulse to scrap the present scheme and start all over again. But there are some areas where changes might be considered.

One such area is the lack of flexibility in the present standard for food additives. As we have seen, the Delaney Clause as well as the adulteration provisions of the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Food, Drug and Cosmetic Act, all set a strict, risk- based standard for food additives. There is no provision in the law as enacted by Congress for the Executive Branch to consider the benefits of a substance. Added poisonous or deleterious substances that may cause harm to humans are prohibited in food regardless of any benefit they may confer. In the case of nitrite, there was a well-established, health benefit--the prevention of botulism--and we believed that it should be considered in fashioning a rational regulatory approach that would protect the general public. But we were told by the Attorney General that the law did not permit us to take benefits into account--not even health benefits.

There would appear to be an easy solution to the type of dilemma that confronted us on nitrite: simply allow the agencies to balance risks against benefits. Again, however, I believe it wise to proceed carefully. Proponents of full-scale risk/benefit analysis often overlook the fact that current categories of substances already reflect social benefit judgments about various classes of food substances. For example, it is

extremely difficult to ban a basic food commodity under the present law because Congress has judged the benefits of these substances to be very high. This is less true of additives. It is entirely appropriate that the Congress should make these fundamental decisions.

A stronger case can be made for having Congress set certain broad guidelines and then permitting the agencies to weigh benefits against risks. But risk-benefit analysis on even a limited basis may not be the panacea it is often cracked up to be. The possible problems include: the increased administrative burdens, and bottlenecks in decisionmaking; the erosion of public confidence in food safety; the uneven distribution of risks and benefits, with one group in society receiving most of the benefits, and another the risks; and the need for a common language and an agreed-upon calculus to compare risks and benefits.

The last two problems could be reduced by a risk-benefit policy that permitted health risks to be compared only to health benefits. Such a policy would have provided us a way out of the dilemma we faced on nitrite. But we should keep in mind that the nitrite matter may prove to be an exception. We should also remember that the present food safety laws have served the people of this nation very well. It may be time for some pruning and trimming. But we do not want to start cutting away at the laws in wholesale fashion simply to satisfy the demands of the moment.

#### IV. SCIENTIFIC EVALUATION

The experience with nitrite over the past 2 years has aroused a good deal of legitimate concern over the adequacy of the scientific review process at FDA and USDA. Commissioner Goyan and I recently received a letter from Senator Thomas R. Eagleton, Chairman of the Appropriations Subcommittee on Agriculture, Rural, and Related Agencies, that summarizes this concern very well. With your permission, Mr. Chairman, I would like to have it placed in the record at this time.

As Senator Eagleton points out, the food safety laws often require regulatory agencies to take prompt action because of new evidence on risks to the public health. But this presents a special challenge. While we must act promptly, we must also be reasonably sure of the evidence so that we do not act precipitously. This problem is not made any easier

by the nature of scientific proof. Perhaps one of the most vexing problems in all of science is trying to decide when, in fact, a hypothesis has been demonstrated. Have all the right variables been controlled for? Have all the spurious correlations been driven away? Has the right kind of statistical analysis been performed? The process of scientific confirmation can go on for many years. Some answers never leave the realm of hypothesis. And "settled truths" can be suddenly overturned.

Fortunately, the standard of proof required by law is usually different than the standard of proof required by science. Legal standards of proof reflect society's need for decisions so that life can go on. The adulteration provisions of the Federal Meat Inspection act, for example, require evidence only that an added substance "may render (a product) injurious to health" (emphasis added). The Courts have interpreted this provision to mean a "reasonable possibility," and not a strict scientific proof.

Perhaps the best statement of the need for regulators to act in the absence of strict scientific proof is found in the decision of the United States Court of Appeals for the District of Columbia Circuit in a case involving EPA regulations on lead emissions:

"While a concerned Congress has passed legislation providing for protection of the public health against gross environmental modifications, the regulators entrusted with the enforcement of such laws have not thereby been endowed with a prescience that removes all doubt from their decisionmaking. Rather, speculation, conflicts of evidence and theoretical extrapolation typify their every action. How else can they act, given a mandate to protect the public health but only a slight or nonexistent data base upon which to draw? "Sometimes, of course, relatively certain proof of danger or harm from such modifications can be readily found. But, more commonly, the statutes--and common sense--demand regulatory action to prevent harm, even if the regulator is less than certain that harm is otherwise inevitable.

"Undoubtedly, certainty is the scientific ideal--to the extent that even science can be certain of its truth. But certainty in the complexities of environmental medicine may be achievable only after the fact, when scientists have the opportunity for leisurely and isolated scrutiny of an entire mechanism. Awaiting certainty

will often allow for only reactive, not preventive regulation. Ethyl Corp. v. EPA, 541 F. 2d 1, 24-25 (D.C. Cir 1976), cert. denied 96 S. CT. 2662."

Obviously, however, regulatory agencies are not free to take action based on the very slightest evidence. There must be some review, some confirmation, even though it may be short of the rigorous proof required by scientific discipline. The challenge to the regulatory agencies, as I see it, is to fashion the type of review procedures that will provide this middle range confirmation necessary for regulatory action. This challenge is not one that is confined to USDA and FDA. I think it is one of the most difficult tasks facing every health regulatory agency.

For this reason, we welcome Senator Eagleton's suggestion that our agencies undertake a study to find alternative ways to improve our peer review mechanisms. Last week we sent him a reply stating that we will seek competitive bids for the type of study he has proposed. We will use FY 1981 funds to carry out this study. This study will assess the procedures now used by FDA and USDA to evaluate scientific data on the toxicity of substances, and consider what changes are needed, including what additional peer review measures should be instituted. Because the study will involve complex, scientific, legal, and philosophical questions, we hope to receive innovative and imaginative proposals. We believe the results will have government-wide importance.

## **V. THE PUBLIC'S RIGHT TO KNOW**

I have left the issue of the public's right to know until the end because it was of central concern to us when we first learned of the results of the Newberne Study back in May 1978. "The public's right to know" is a loaded phrase, and I do not wish to invoke it as any sort of moral justification for our decision to announce the Newberne findings. What I wish to emphasize is a simple matter of fact: regulatory agencies must now go about their work in an environment of total openness. In a recent editorial on the subject of the nitrite study and freedom of information, the "Washington Post" referred to this bias as "our let-it-all-hang-out style of government." The "Post" attributes this open style to the effect of the Freedom of Information Act and to post-Watergate

to the effect of the Freedom of Information Act and to post-Watergate sensitivities about coverups. We could probably spend several days on this subject. For right now, however, the question worth examining is the effect that all this had on our decision in August 1978 to go public with the Newberne study.

There was never really any question about having to release the results of the study. Once an agency has contracted for a study and then accepted it, it is virtually impossible under the Freedom of Information Act to withhold its release. Given the rather widespread knowledge that the Newberne study was underway, and the intense interest in any study that concerns a potential carcinogen, we inevitably would have been faced with a Freedom of Information request. We were certain that, at some point, we would be legally required to release the Newberne findings.

The real questions were when to announce the findings, and in what manner. In hindsight, it is clear that the ideal time to release the study would have been after the thorough review of the pathology of the tissue slides. But back in the summer of 1978 this choice was not available. We could not predict that the review of the pathology would undermine the results of study. The best indications were just the reverse. Given the significant scope of the study and the previous record of the researcher, the safest prediction was that the results would be confirmed. We would then have been faced with the question of why we had kept the study under wraps for such a lengthy period.

On the matter of timing, it also was unrealistic to expect that we could keep the results a secret for any period of time. All of us must live with that time-honored Washington institution known as the news leak. When we began to develop a plan for releasing the study, we knew that it was only a matter of time before reports on the study would begin appearing in the media. This knowledge gave our deliberations some sense of urgency. As I have mentioned, "Food Chemical News" carried a story on the findings almost as soon as they were reported to us. We felt there was the greatest potential for alarm, both to consumers and to industry, if reports of the study were leaked out to the public in piecemeal and distorted fashion.

Therefore, we believed that the manner in which the Newberne findings were released was crucial. It is always difficult to decide the

best way to inform the public about a potential health risk. But the evidence on nitrite presented an even more difficult situation because it involved competing health risks: the potential of causing cancer, and the potential risks of botulism. It was important to adopt a public information strategy that attempted to explain as fully as possible the complexity of the issue. We had to present the Newberne findings for what they were, but at the same time make it clear that they still had to be confirmed. We also had to point out that there might be competing health risks. We had to assure consumers that we were proceeding in a manner that would protect the public health, but at the same time allay the fears of consumers and industry that we would take action that might create another risk to public health and that could cause severe economic hardships.

These concerns lay behind our decision to announce a tentative regulatory plan for dealing with the problem of nitrite. We felt it important to let both consumers and industry know where we were headed. The most alarming action we could have taken would have been to announce the Newberne study without any explanation of what we planned to do about it. Consumers would have feared that the government was doing nothing to protect the safety of the food supply, and industry would have feared that they government would suddenly do too much. Under the circumstances, I think we took the only sensible course.

## VI. THE FUTURE

As we look back on the difficult decisions that confronted us two years ago, we can only be grateful that the original Newberne findings were not borne out by the later review. But it would be a grave mistake for us now to be lulled into a false sense of security. As I mentioned earlier, the scientific community remains concerned over the possibility that nitrite can combine with other substances in the human digestive tract to form the powerful carcinogen known as nitrosamines.

The inescapable lesson to be drawn from our recent experience is the folly of becoming excessively dependent on the use of one substance. There is little wisdom in having an entire industry and one-tenth of the nation's food supply dependent on the use of a single food additive. If that substance is thrown into question, then there is

nowhere else to turn. I want the Committee to know that we are taking steps to be prepared the next time around. In the present fiscal year we are devoting \$2 million to the search for alternatives to nitrite. Considering the importance of nitrite to the meat industry and to consumers, I can think of no research that is more vital.

We must continue to do everything we can to plan ahead to anticipate possible problems that all too quickly can become harsh reality. This is what we tried to do when first confronted with the evidence on nitrite, and I believe it is what the Congress and the public generally expects of rational managers. But, as we have seen from the experience with nitrite, we should not always expect food safety regulation to be a smooth, happy process. Emotions often run high, because the economic stakes and the health consequences can be high. Unfortunately, the evidence we must work with is not always clear cut, and it is possible for reasonable people to disagree. I think it is safe to predict that FDA and USDA will continue to face difficult decisions in the less than perfect world they inhabit. We will strive to be worthy to the challenge.

Mr. Chairman, this completes my testimony.

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# Press Releases

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## MILK TO BE SUPPORTED AT 80 PARITY

WASHINGTON, Sept. 19--Manufacturing milk will be supported at 80 percent of the Oct. 1 parity price, according to Ray Fitzgerald, executive vice president of the U.S. Department of Agriculture's Commodity Credit Corporation.

The exact support price will be determined after USDA's Sept. 30 "agricultural prices" report is released. However, Fitzgerald said, USDA economists expect the support price will be about \$12.73 per hundredweight for milk with a milkfat content of 3.5 percent, compared with the present support of \$12.07. The \$12.73 support price is equivalent to \$13.03 for milk with 3.67 percent milkfat, the U.S. annual average, compared with the present support of \$12.36 at average test, he said.

Fitzgerald said the law requires the price of milk be supported between 80 and 90 percent of parity in order to assure an adequate supply of milk, to reflect changes in the cost of production, and to assure dairy farmers an income that will enable them to maintain sufficient productive capacity to meet anticipated future needs.

To enable manufacturing plants, on the average, to pay producers at least the support price for their milk, the government offers to buy butter, cheese and nonfat dry milk at announced prices. The government purchase prices will be announced at the same time as the milk support price, Fitzgerald said.

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# Press Releases

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## USDA AMENDS EXPORT SALES REPORTING REQUIREMENTS FOR USSR

WASHINGTON, Sept. 24--The quantities of wheat and corn sold to the Soviet Union that are reportable on a daily basis are being reduced from 100,000 to 25,000-metric tons, effective Sept. 16, Kelly Harrison, general sales manager for the U.S. Department of Agriculture, said today.

Although the current regulations require all wheat and corn sales to the Soviet Union be reported, they permit as much as a week's delay in the reporting of sales smaller than 100,000 tons, Harrison said.

The change revises Section V of the Notice to Exporters of the export sales reporting instructions as revised April 1980, and will affect transactions made during the fifth year of the U.S.-USSR grain supply agreement.

"It should permit closer monitoring of the level of sales to the Soviet union in view of the 8-million-ton limitation of fifth year purchases and exports, and provide more timely and accurate data to the public, Harrison said.

For more information on the revision, contact Richard Finkbeiner (202) 447-5651.

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# Press Releases

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## USDA VETERINARIANS FIND DISEASED BIRDS IN 14 STATES

WASHINGTON, Sept. 25--Exotic Newcastle disease has been diagnosed in pet birds in 14 states, all traced back to a Miami, Fla., wholesale exotic bird dealer, a U.S. Department of Agriculture veterinarian said today.

Jerry Mason, who is directing eradication efforts for USDA's Animal and Plant Health Inspection Service, said the disease has been diagnosed in Arizona, Arkansas, California, Delaware, Florida, Hawaii, Illinois, Maine, Michigan, Minnesota, Missouri, Ohio, Texas and Vermont.

APHIS veterinarians, working out of regional emergency task force offices, are tracking down birds sold by infected pet shops in those states. The emergency task force offices are located in Miami Springs, Fla., Santa Ana, Calif., Hyattsville, Md., Topeka, Kans., and Austin, Texas.

To date, about 16,000 infected or exposed birds have been destroyed in 300 premises to stop the spread of the exotic Newcastle disease virus, Mason said. Bird owners will be paid about \$800,000 to help compensate for these losses.

Since Sept. 10, when the disease was diagnosed in the Miami area, APHIS veterinarians have located, killed and submitted to the diagnostic laboratory all but a very few of the birds shipped from the Miami area. According to Mason, fine cooperation from the entire pet bird industry and local news media has been instrumental in helping locate infected and exposed birds as rapidly as possible.

"Although we've found infected pet birds in poultry production areas," Mason said, "there has been no spread to commercial poultry. The poultry industry is taking every precaution to make sure that our poultry are protected."

Exotic Newcastle disease is not a health hazard to people who eat poultry and eggs, but the disease can cause very high mortality in all classes of poultry. The disease can infect people who handle infected birds, causing transitory eye inflammation or flu-like symptoms, which should be treated by a physician, Mason said.

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## USDA ANNOUNCES LOAN PROGRAM FOR AFLATOXIN CONTAMINATED CORN

WASHINGTON, Sept. 19--Acting Secretary of Agriculture Jim Williams today said eligible North Carolina corn farmers may apply for recourse loans of \$1.70 per bushel on corn contaminated with aflatoxin, a cancer-producing agent.

The U.S. Food and Drug Administration prohibits the use for human food and animal feeds of contaminated corn that contains more than 20 parts of aflatoxin per billion.

Williams said the continued hot, dry weather in North Carolina has produced conditions favorable for the development of the mold *aspergillus flavus*, which produces aflatoxin. Williams also said USDA is watching conditions in other states and will institute similar corn loan programs as conditions warrant.

Williams said offering farmers loans on aflatoxin-contaminated corn will remove the pressure on a producer to try to sell this corn, which would be both illegal and detrimental to humans and animals.

FDA is considering a proposal to allow farmers to blend aflatoxin-contaminated corn with good corn and feed the blended corn to certain livestock, Williams said, but no decision yet has been made. FDA approved on a one-time basis an arrangement to use up to 100 parts per billion in a previous aflatoxin outbreak in corn.

pp Williams said a farmer harvesting aflatoxin-contaminated corn and receiving a Commodity Credit Corporation-loan on the corn will have the option at the end of the loan period (9 months) of (1) paying back the loan principal plus interest at an annual rate of 11-1/2 percent, or (2) destroying the contaminated corn, applying for low yield disaster payment and paying to CCC the remaining liability plus interest.

Corn farmers who signed up for the 1980 feed grain program and are otherwise eligible may apply for loans on their contaminated corn by contacting a county office of USDA's Agricultural Stabilization and Conservation Service.

Williams is acting secretary while Secretary of Agriculture Bob Bergland is out of Washington.